

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparison the results of induction of vaginal misoprostol with Foley catheter in prolonged pregnancy with unripe cervix

#### Protocol summary

##### Summary

The aim of this study is to compare the results of induction of vaginal misoprostol with Foley catheter in prolonged pregnancy with unripe cervix. 60 pregnant women with prolonged gestation (gestational age greater than 40 weeks) will be included in the study who are referred to the Sayyad Shirazi Hospital in Gorgan. By using of block randomization pregnant women will be allocated into two groups: Foley Catheter (30 patients) and Vaginal Misoprostol (30 patients). In the present study, blinding will not implement. The Foley Catheter will be exposed to direct ventral speculum. Cervix will be cleaned by antiseptic solution. The Foley catheter size 16 is inserted into the cervix, and filled with 30 ml of normal saline sterile balloon. Foley Catheter will be placed under soft pulling for up to 12 hours. In the second group, misoprostol 25 micrograms are used vaginally in the posterior foreskin for the patient and will be repeated every 4 hours to a maximum of 200 micrograms until reaching the appropriate dilatation of the cervix. Proper contraction is defined at least three contraction every ten minutes with suitable strength.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017052710340N13**

Registration date: **2017-06-26, 1396/04/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-26, 1396/04/05

##### Registrant information

**Name**

Mohammad Aryaie

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 277 1798

##### Email address

aryaie@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Golestan university of medical sciences

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### Expected recruitment end date

2017-06-20, 1396/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the results of induction of vaginal misoprostol with Foley catheter in prolonged pregnancy with unripe cervix

##### Public title

Comparison of vaginal Misoprostol versus Foley catheter for labor induction

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Cephalic presentation; healthy amnion; Bishop score less than 6; inappropriate cervix; inappropriate uterine contractions; normal fetal heart rate. Exclusion criteria was considered as : Pelvic dystocia; fetal weight more than 4 kg; incompatibility of

fetal head with maternal pelvis ; placenta praevia;  
unexplained vaginal bleeding; the parity more than five;  
fetal anomaly; previous uterine scar; any situation that  
makes vaginal delivery impossible.

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 60

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Golestan University of Medical  
Science

##### Street address

4 Kilometer of Gorgan-sari Road, Falsafi educational  
campus, Vice Chancellor of Technology and  
Information, Gorgan

##### City

Gorgan

##### Postal code

#### Approval date

2017-05-16, 1396/02/26

#### Ethics committee reference number

IR.GOUMS.REC.1396.23

## Health conditions studied

### 1

#### Description of health condition studied

pregnancy

#### ICD-10 code

O00-O99

#### ICD-10 code description

Pregnancy, childbirth and the puerperium

## Primary outcomes

### 1

#### Description

Labor induction

#### Timepoint

The first, second and third phase of delivery

#### Method of measurement

Stopwatch

## Secondary outcomes

### 1

#### Description

Apgar

#### Timepoint

The first minute after the baby is born

#### Method of measurement

Apgar score

### 2

#### Description

Bleeding

#### Timepoint

After delivery

#### Method of measurement

The number of bleeding pads

## Intervention groups

### 1

#### Description

Foley catheter 16

#### Category

Treatment - Other

### 2

#### Description

25 mcg tablets of misoprostol and posterior vaginal fornix

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sayyad Shirazi hospital

##### Full name of responsible person

Ghazal Goli

##### Street address

Shahid Sayyad Shirazi hospital, Shahid Sayyad Shirazi  
Street, Gorgan City, Golestan Province

##### City

Gorgan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Golestan University of Medical Sciences

**Full name of responsible person**

Mohsen Saeedi

**Street address**

4 Kilometer of Gorgan-Sari Road, Falsafi educational campus, Vice chancellor for research, Gorgan

**City**

Gorgan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Golestan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Golestan University of Medical Science

**Full name of responsible person**

Ghazal Goli

**Position**

Obstetricians

**Other areas of specialty/work****Street address**

4 Kilometer of Gorgan-Sari Road, Falsafi educational campus, Vice chancellor of research, Gorgan

**City**

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**Postal code****Phone**

+98 17 3242 4377

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Golestan University of Medical Sciences

**Full name of responsible person**

Mohamma Aryaie

**Position**

MSc in Epidemiology

**Other areas of specialty/work****Street address**

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aryaie@goums.ac.ir

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*